

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Bayer Corp., Agriculture Division, Animal Health to Bayer HealthCare LLC, Animal Health Division.

DATES: This rule is effective [*insert date of publication in the **Federal Register***].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: dnewkirk@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, has informed FDA of a change of name to Bayer HealthCare LLC, Animal Health Division. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A), because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for “Bayer Corp.” and by alphabetically adding an entry for “Bayer HealthCare LLC”; and in the table in paragraph (c)(2) by revising the entry for “000859” to read as follows.

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* *
Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	000859
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * *
000859	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201
* *	* *

Dated: March 21, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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